Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0502333	04/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Christus Spohn Hospital Kleberg Lab	1311 E General Cavazos Blvd, Kingsville, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5026 - 42 C.F.R. 493.1217 Condition: Immunohematology D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director: Moderate Complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a surveyor observation, review of laboratory policy, proficiency testing records, and confirmed in an interview, the laboratory failed to test proficiency testing samples the same number of times that it routinely tests patient samples for 3 of 3 proficiency test (PT) events reviewed in 2022 for i-STAT blood gas testing. The findings included: 1. In a tour of the laboratory on 4/4/2023 at 09:30 hours, the surveyor noted the following i-STAT used in blood gas analysis: Serial: 337410 TP 11 stated that the i-STAT in use (serial: 337410) was previously the secondary analyzer and that the primary analyzer (serial: 351409) was out of service. 2. Review of the laboratory policy titled "Arterial Blood Gas Manual: Quality Assurance", section "Proficiency Testing" had the following statement: "All survey materials will be tested, when possible, in exactly the same manner as patient samples and as part of the regular workflow." 3. Review of the laboratory PT records, and instrument printouts, for 2022, had the following PT specimens performed on the primary and secondary i-STAT analyzer. AQI-A 2022 Critical Care Blood Gas, iSTAT - CAP

	Sample: AQI-A 1 Performed on 02MAR2022 at 16:55, serial: 351409 Performed on 02MAR2022 at 16:55, serial: 337410 Sample: AQI-A 2 Performed on 02MAR2022 at 17:04, serial: 351409 Performed on 02MAR2022 at 17:04, serial: 337410 Sample: AQI-A 3 Performed on 02MAR2022 at 17:10, serial: 351409 Performed on 02MAR2022 at 17:10, serial: 337410 Sample: AQI-A 4 Performed on 02MAR2022 at 17:14, serial: 351409 Performed on 02MAR2022 at 17:15, serial: 337410 Sample: AQI-A 5 Performed on 02MAR2022 at 17:20, serial: 351409 Performed on 02MAR2022 at 17:20, serial: 337410 AQI-B 2022 Critical Care Blood Gas, iSTAT - CAP Sample: AQI-B 6 Performed on 09JUL2022 at 00:42, serial: 351409 Performed on 09JUL2022 at 00:42, serial: 337410 Sample: AQI-B 7 Performed on 09JUL2022 at 00:47, serial: 351409 Performed on 09JUL2022 at 00:47, serial: 337410 Sample: AQI-B 8 Performed on 09JUL2022 at 00:52, serial: 351409 Performed on 09JUL2022 at 00:52, serial: 337410 Sample: AQI-B 9 Performed on 09JUL2022 at 00:57, serial: 351409 Performed on 09JUL2022 at 00:57, serial: 337410 Sample: AQI-B 10 Performed on 09JUL2022 at 01:02, serial: 351409 Performed on 09JUL2022 at 01:02, serial: 337410 AQI-C 2022 Critical Care Blood Gas, iSTAT - CAP Sample: AQI-C 11 Performed on 03NOV2022 at 19:33, serial: 351409 Performed on 03NOV2022 at 19:33, serial: 337410 Sample: AQI-C 12 Performed on 03NOV2022 at 19:38, serial: 351409 Performed on 03NOV2022 at 19:38, serial: 337410 Sample: AQI-C 13 Performed on 03NOV2022 at 19:43, serial: 351409 Performed on 03NOV2022 at 19:43, serial: 337410 Sample: AQI-C 14 Performed on 03NOV2022 at 19:49, serial: 351409 Performed on 03NOV2022 at 19:49, serial: 337410 Sample: AQI-C 15 Performed on 03NOV2022 at 19:54, serial: 351409 Performed on 03NOV2022 at 19:54, serial: 337410 Surveyor queried on 4/4/2022 at 12:30 if patients were tested on each analyzer in routine testing, TP 11 stated patients were only tested on one analyzer without routine repeat testing. 4. In an interview on 4/4/2022 at 12:35, in the respiratory department, TP 11 confirmed that patients were not routinely tested on each i-STAT analyzer and that the PT should not have been tested as such. This confirmed the findings.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the laboratory and facility blood product transfusion policies, facility blood transfusion forms, a random review of patient transfusion records (01/01/2023-01/15/2023 and 08/01/2023-08/15/2023), and confirmed in staff interview, it was revealed the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 6 of 25 patients that received blood products. Findings Included: 1. Review of facility policy, "Blood Transfusion Administration Procedure" (Revised 05/2022) revealed the following: "13. To initiate, maintain and discontinue the transfusion of unit of blood products:.. b. Document pre-transfusion vital signs. ..g. The RN should remain with or be in a position to closely observe the patient for at least the first 15 minutes of infusion. Signs and symptoms of a fatal transfusion reaction usually occur within this time period. h. The RN or LVN will periodically observe and assess patient for symptoms of transfusion reactions. i. Additional vital signs should be documented as follows: i.

Just prior to initiating the infusion. ii. Within fifteen (15) minutes after transfusion has started. iii. Every 30 to 60 minutes or more frequently as indicated by patient's condition. iv. At the end of the transfusion. v. One-hour post-transfusion. ..o. Signs and symptoms as described in the next section may occur several hours to several days post transfusion and should be reported to the Transfusion Service for investigation. 14. Transfusion Reaction a. Complications to a transfusion may include the following: i. Urticaria ii. Chills iii. Temperature 2 degrees over baseline iv. Headache v. Nausea vi. Pain vii. Shortness of breath 2. Review of the laboratory policy, "Transfusion Reaction Investigation" (Version 5; Effective 11/05/18) revealed the following: "Procedure: ..8. Review clinical signs and symptoms pre- and post-transfusion. See guidelines to classification of transfusion reaction." 3. During an interview with the regional blood bank supervisor on 04/04/2023 at 1426 hours in the laboratory, the supervisor was asked to provide the guidelines for transfusion reaction classification. The following facility guidelines were provided: "Transfusion Reaction Report Complete information below when a transfusion complication occurs. Type of complication: Urticaria; Chills; Fever; Headache; Shortness of breath; Cyanosis; Nausea; Back Pain; Pain at infusion site; Increased pulse rate; Decreased blood pressure; Significant increase in systolic BP (greater that 40 mm/Hg)" The facility, laboratory policies and facility guidelines failed to define criteria for respiration rate to indicate a transfusion reaction. The facility, laboratory policies and facility guidelines failed to define criteria for pulse rate changes. The laboratory policy and facility guidelines failed to define criteria for an increase in temperature to indicate a transfusion reaction. The facility policy failed to define criteria for systolic blood pressure changes. 4. A random review of blood product administration patient records (01/01/2023-01/15/2023 and 08/01/2023-08/15/2023), revealed the following 6 of 25 patients in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. Patient 0103:BB00041R Unit Number: W230821720320; Red Blood Cells Transfusion Begin Date/Time: 01/05/2022/0835 Transfusion End Date/Time: 01/05/2022/1002 Time: 1002 hours Transfusion comment: Time: 1002 hours: PATIENT TRANSPORTED TO EMERGENCY ROOM. PATIENT WAS EXPERIENCING SOB. The patient experienced shortness of breath following the start of a transfusion and was transported to the emergency room. Per facility policy, indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. b. Patient 0106:BB00045S Unit Number: W230821164034; Red Blood Cells Transfusion Begin Date/Time: 01/06/2022/1620 Transfusion End Date/Time: 01/06/2022/1832 Pre-Transfusion Vitals documented at 1617: Temperature: 98.0; Blood Pressure: 125/58; Pulse/HR 85; Respiratory rate: 18 Vitals documentation at 1832: Temperature: 98.0; Blood Pressure: 173/74; Pulse/HR 83; Respiratory rate: 18 The patient had a blood pressure increase of 48 mmHg from vitals documented at 1617 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. c. Patient 0109:BB00045S Unit Number: W230821369206; Red Blood Cells Transfusion Begin Date/Time: 01/11/2022/0054 Transfusion End Date/Time: 01/11/2022/0311 Pre-Transfusion Vitals documented at 0139: Temperature: 98.7; Blood Pressure: 107/52; Pulse/HR 88; Respiratory rate: 12 Vitals documentation at 0310: Temperature: 98.7; Blood Pressure: 159/72; Pulse/HR 100; Respiratory rate: 20 The patient had a blood pressure increase of 52 mmHg from vitals documented at 0310 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. d. Patient 0808:BB00045S Unit Number: W230822453272; Red Blood Cells Transfusion Begin Date/Time: 08/08/2022/1141 Transfusion End Date/Time: 08/08/2022/1515 Pre-Transfusion Vitals

	documented at 1145: Temperature: 97.8; Blood Pressure: 94/64; Pulse/HR 112; Respiratory rate: 24 Vitals documentation at 1500: Temperature: 98.1; Blood Pressure: 136/76; Pulse/HR 94; Respiratory rate: 21 The patient had a blood pressure increase of 42 mmHg from vitals documented at 1500 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. e. Patient 0810:BB00087R Unit Number: W230822682435; Red Blood Cells Transfusion Begin Date/Time: 08/10/2022/2250 Transfusion End Date/Time: 08/11/2022/0042 Pre-Transfusion Vitals documented at 2342: Temperature: 99.1; Blood Pressure: 115/58; Pulse/HR 87; Respiratory rate: 20 Vitals documentation at 0042: Temperature: 99.8; Blood Pressure: 158/67; Pulse/HR 87; Respiratory rate: 18 The patient had a blood pressure increase of 43 mmHg from vitals documented at 1500 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. f. Patient 0815:BB00029R Unit Number: W230822682658; Red Blood Cells Transfusion Begin Date/Time: 08/15/2022/1128 Transfusion End Date/Time: 08/15 /2022/1351 Pre-Transfusion Vitals documented at 1213: Temperature: 98.2; Blood Pressure: 105/57; Pulse/HR 78; Respiratory rate: 16 Vitals documentation at 1451 (1 hour post vitals): Temperature: 98.4; Blood Pressure: 152/52; Pulse/HR 86; Respiratory rate: 16 The patient had a blood pressure increase of 47 mmHg from vitals documented at 1451 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. 5. During an interview with the blood bank regional lead technologist on 04/05/2023 at 1324 hours in the conference room, the lead technologist confirmed the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 6 of 25 patients that received blood products. Word Key RN: Registered Nurse LVN: Licensed Vocational Nurse HR: Heart Rate mm/Hg: millimeters of mercury SOB: Shortness of breath
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, review of laboratory records, and confirmed in interview, the laboratory failed to retain documentation of test records for the Avoximeter (AVOX) 4000 used in co-oximetry testing for 2021 and 2022. The findings included: 1. In a tour of the laboratory on 4/4/2023 at 09:30 hours, the surveyor noted the following instrument used in Co-Oximetry testing: AVOX 4000: SN 50207 2. Review of the laboratory policy titled "Arterial Blood Gas Manual, Analyzing the Blood Gas Sample" section 2. "Analyzing Co-Oximetry Specimens on the AVOX 4000:" stated the following: "q. Place results printed from AVOX printer in door pocket in ABG Lab for review by the Cardiopulmonary Manager or Clinical Specialist." 3. Surveyor queried as to annual patient test volume for the AVOX 4000 and TP 11 stated, on 4/4/2023 at 11:05 hours, that they estimated five patients were done annually. Surveyor queried for the testing records for 2021 and 2022. TP 11 stated that the records would be hard to pull from the laboratory information system (LIS), but that they would attempt retrieval. At the time of the

	inspection exit on 4/6/2023 at 13:40, the records had not been produced. This confirmed the findings.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Immunohematology records, patient records, and interviews the laboratory failed to meet applicable requirements in the specialty of Immunohematology (refer to D5555 and D5559).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 2 of 2 Technical Consultants (TC-1 and TC-2) performing moderate complexity oversight. Findings Included: 1. Review of laboratory policy, "Employee Competency Evaluation" (Version 4; Effective: 10/05/2018" revealed the following: "The laboratory has defined the following job descriptions: Medical director, Laboratory Manager, Lead Technologist, Medical Technologist, Medical Laboratory Technician, Medical Technologist Student, Phlebotomist, Lab Aide. New employees competence is monitored for the first three months and evaluated thereafter. All employees performance is assessed annually in their job specific performance evaluation." 2. Review of the Centers for Medicare and Medicaid (CMS -209) form submitted at the time of survey, 04/04 /2023, revealed 2 technical consultants (TC-1 and TC-2) for moderate complexity testing. 3. Review of personnel records revealed no documented competency assessment for the duties performed as a technical consultant in 2021 and 2022. 4. On 04/04/2023 at 1148 hours in the conference room, the laboratory was asked to provide a documentation policy of when and how a competency assessment was to be performed on the technical consultant. No documentation was provided. This confirmed the above findings. II. Based on review of the laboratory's policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 2 of 2 General Supervisors (GS-1 and GS-2) performing high complexity oversight. Findings Included: 1. Review of laboratory policy, "Employee Competency Evaluation" (Version 4; Effective: 10/05/2018" revealed the following: "The laboratory has defined the following job descriptions: Medical director, Laboratory Manager, Lead Technologist, Medical Technologist, Medical Laboratory

	Technician, Medical Technologist Student, Phlebotomist, Lab Aide. New employees competence is monitored for the first three months and evaluated thereafter. All employees performance is assessed annually in their job specific performance evaluation." 2. Review of the Centers for Medicare and Medicaid (CMS -209) form submitted at the time of survey, 04/04/2023, revealed 2 general supervisors (GS-1 and GS-2) for high complexity testing. 3. Review of personnel records revealed no documented competency assessment for the duties performed as a general supervisor in 2021 and 2022. 4. On 04/04/2023 at 1148 hours in the conference room, the laboratory was asked to provide a documentation policy of when and how a competency assessment was to be performed on the general supervisors. No documentation was provided. This confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for 13 of 13 analytes tested on the MEDTOXscan analyzer in 2021 and 2022. The finding included: 1. A review of the laboratory's test menu revealed the following 13 analytes were tested on the MEDTOXscan analyzer in 2021 and 2022: Tetrahydrocanabinol Phencyclidine Cocaine Methamphetamine Opiates Amphetamine Benzodiazepine Barbiturates Tricyclic antidepressants Methadone Oxycodone Propoxyphene Buprenorphrine 2. A review of the laboratory's College of American Pathologists' and American Proficiency Institute's proficiency testing records from 2021 and 2022 revealed the laboratory failed to include analytes tested on the MEDTOXscan analyzer as part of the proficiency testing. 3. The laboratory was asked to provide documentation of performing twice annual accuracy assessments in 2021 and 2022 for the identified analytes. No documentation was provided. 4. An interview with general supervisor number 2 (as listed on Form CMS 209) on 04/05/2023 at 1240 hours in the laboratory - after her review of the records- confirmed the findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions for the Architect STAT Troponin-I assay, review of the manufacturer's instructions Architect Alkaline Phosphatase assay, review of the manufacturer's instructions for the Architect Glucose assay, review of the manufacturer's instructions for the Architect ICT (Na, K, Cl) assay, review of

patient test records, and staff interview, it was revealed the laboratory failed to have a mechanism in place to ensure samples received by the laboratory were kept at a temperature that maintained sample stability. The findings included: 1. A review of the manufacturer's instructions for the Architect STAT Troponin-I assay (G1-0467 /R11, B2K4Y0) under the section titled "Specimen Storage" revealed: Room Temperature 8 hours 2 - 8C less than 72 hours 2. A review of the manufacturer's instructions for the Architect Alkaline Phosphatase assay (307217/R01, B7DVF0) under the section titled "Specimen Storage" revealed: 20 - 25C 7 days 3. A review of the manufacturer's instructions for the Architect Glucose assay (G95983RO2, B3L8C0) under the section titled "Specimen Storage" revealed: 20 - 25C 2 days 4. A review of the manufacturer's instructions for the Architect ICT (Na, K, Cl) assay (306954/R04, B2P3X0) under the section titled "Specimen Storage" revealed: Sodium 20 - 25C 2 weeks Potassium 20 - 25C 1 week Chloride 20 - 25C 7 days 4. A sampling of patient samples received from outside the facility from December 2022 to April 2023 identified the following specimens for which the laboratory did not have a mechanism in place to ensure the samples were received at a temperature that maintained sample stability: a) Date: 12/09/2022 Acct Number: AQ0001404972 Tests: Sodium Potassium Chloride Glucose No documentation sample was kept at 20 - 25C during transport. b) Date: 02/17/2023 Acct Number: AQ0001411497 Tests: Sodium Potassium Chloride Glucose Alkaline Phosphatase No documentation sample was kept at 20 - 25C during transport. c) Date: 01/20/2023 Acct Number: AQ0001408870 Test: Troponin Time from collection to receipt: 12 hours 15 minutes No documentation of temperature the sample was received at to ensure it was received at 2 - 8C. d) Date: 02/01/2023 Acct Number: AQ0001409931 Test: Troponin Time from collection to receipt: 10 hours 36 minutes No documentation of temperature the sample was received at to ensure it was received at 2 - 8C. e) Date; 04/04/2023 Acct Number: AQ0001415875 Test: Troponin Time from collection to receipt: 10 hours 14 minutes No documentation of temperature the sample was received at to ensure it was received at 2 - 8. f) Date: 04/05/2023 Acct Number: AQ0001413450 Test: Troponin Time from collection to receipt: 11 hours 16 minutes No documentation of temperature the sample was received at to ensure it was received at 2 - 8. 5. The laboratory was asked to provide documentation of monitoring the temperature of samples received in the laboratory. No documentation was provided. 6. An interview with general supervisor number 1 (as listed on Form CMS 209) on 04/04/2023 at 1600 hours in her office revealed the laboratory did not monitor the temperature of samples received from other facilities. This confirmed the findings. Key Na - sodium K - potassium Cl - chloride 44278 II. Based on direct observation, review of laboratory policy, random review of patient fibrinogen results (11/2022-12/2022) and staff interview, it was revealed that the laboratory failed to follow their own written policy for fibrinogen specimen acceptability for 2 of 12 patient reviewed in 11/2022 and 12 /2022. Findings Included: 1. During a tour of the laboratory on 04/05/2023 at 1535 hours, the inspector observed 1 ACL Top 350 Coagulation Analyzer processing patient specimens. (SN:19081560) 2. Review of laboratory policy, "ACL TOPS Q.F. A FIBRINOGEN" (Version 1.0; Effective: 01/16/2020) revealed the following: "D. Stored Specimen Stability: 1. Plasma may be analyzed up to 4 hours, if stored at room temperature. 2. If testing is not completed within 4 hours or if shipment is required, the plasma may be stored frozen at less than or equal to -18 Celsius or below for up to 4 weeks if frozen within 4 hours of blood collection." 3. Review of patient fibrinogen reports revealed 2 of 12 patients that were tested beyond the 4 hour stability: a. Patient 1114:CG00148S Ordered: Fibrinogen Collected Date/Time: 11/14/2022/0610 Received Date/Time: 11/14/2022/1211 Elapsed time: 6 hours and 1 minute b. Patient 1114:CG00148S Ordered: Fibrinogen Collected Date/Time: 12/11/2022/0727 Received Date/Time: 12/11/2022/1319 Elapsed time: 5 hours and 52 minutes 4.

	During an interview with the hematology regional lead technologist on 04/06/2023 at 0930 hours in the conference room, the supervisor was asked to provide documentation of the above specimens being frozen after the 4 hour stability, before being analyzed. No documentation was provided. This confirmed the laboratory failed to follow their own written policy for fibrinogen specimen acceptability for 2 of 12 patient reviewed in 11/2022 and 12/2022.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies, review of laboratory records, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to meet analytical system requirements. The findings include: 1. The laboratory failed to follow its policy for performing sampling mode comparisons (refer to D5401 I). 2. The laboratory failed to follow its own policy for hematoxylin and eosin (H&E) staining for frozen section processing (refer to D5401 II). 3. The laboratory failed to define, in policy, the intended reactivity for Hematoxylin and Eosin (H&E) staining to ensure predictable staining characteristics of quality control slides for 173 of 173 patients tested in 2021 and 2022 (refer to D5403). 4. The laboratory failed to follow the manufacturer's instructions to ensure samples did not contain platelets (refer to D5411 I). 5. The laboratory failed to follow the manufacturer's instructions to ensure urine samples were within a pH value of 3 - 11 prior to testing (refer to D5411 II). 6. The laboratory failed to follow manufacturer's instructions for establishing the reference interval (patient normal range) for PT reagent (RecombiPlastin) upon installation for 2 of 2 ACL Top Family Series coagulation analyzers in 2019 (refer to D5411 III). 7. The laboratory failed to follow the manufactures instructions for the processing of urine for urine sediment examination for 17 of 17 random patients reviewed in November 2022 (refer to D5411 IV). 8. The laboratory failed to have documentation of performing required studies for 2 of 2 modified FDA-approved assays (refer to D5423). 9. The laboratory failed to have documentation of performing daily maintenance on 3 of 61 days (refer to D5429). 10. The laboratory failed to have a mechanism in place to monitor QC for accuracy and precision over time for the Avoximeter (AVOX) 4000 used in co-oximetry testing for 12 of 12 months (refer to D5441). 11. The laboratory failed to perform two levels of quality control each day of patient testing for 2 out of 59 days for HIV testing (refer to D5447). 12. The laboratory failed to have documentation of performing quality control testing each day of patient testing for 57 of 64 test days on the MEDTOXscan analyzer (refer to D5449). 13. The laboratory failed to test quality control materials as required for body fluid cell counts (refer to D5543). 14. The laboratory failed to have documentation of two instrument comparisons being performed in 2021 and 2022 between the Architect Plus ci4000 analyzer and the MEDTOXscan analyzer (refer to D5775). 15. The laboratory failed to accurately document the date of specimen receipt into the laboratory for 4 of 20 patients (refer to D5787).

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of policies and procedures and interview of testing personnel, the laboratory failed to perform result comparisons between the two modes (open and closed) at least once every six months on the Sysmex hematology analyzers as defined in their own policy. The findings included: 1. Review of policy H01 Hematology Quality Assurance (effective 02/99) found on page 6 under the heading Result Comparison:"At least once every six months a comparison between the two modes (open and closed) will be run on the Sysmex XN2000 A and B." 2. The laboratory tested 19,608 patient specimens for Complete Blood Counts using the Sysmex XN Hematology analyzers in 2022. 3. During interview of General Supervisor 1 on the CMS Report 209 Laboratory Personnel Report conducted April 5, 2023 at 11:55 she confirmed that the laboratory did not perform comparison of results between the open and closed modes on the Sysmex Hematology analyzers at least once every 6 months as written in their own procedure. 45469 II. Based on surveyor observation, review of laboratory policy, patient test records, and confirmed in interview, the laboratory failed to follow its own policy for hematoxylin and eosin (H&E) staining for frozen section processing for 173 of 173 patients tested in 2021 and 2022: The findings included: 1. In a tour of the pathology room on 4/5/2023 at 16:10, the surveyor noted the following staining protocol posted above the sink: Solution - Time 1. Frozen Fix - 5-10 seconds 2. H2O - 5 seconds 3. Cryo-Hematoxylin - 1 minute 4. H2O - 10 Seconds 5. Cryo-Acid Alcohol - 1 seconds 6. H2O - 5 seconds 7. Cryo-Bluing Solution - 2 seconds 8. H20 - 10 seconds 9. Cryo-Eosin - 10 seconds 10. Ethanol - 10 seconds 11. Ethanol - 10 seconds 12. Clear Rite3 - 10 seconds 13. Clear Rite3 - 10 seconds 14. Coverslip & Cover Seal or similar mounting medium 2. Review of the laboratory policy titled "Pathology Manual: Frozen Sections", section III "Staining the slides" had the following instruction: "A. Flood the slide with fixative for 5 - 10 seconds. 1. Rinse the slide with deionized water. B. Stain the slide with acidified Hematoxylin for approximately 1 minute. 1. Rinse off the excess stain in deionized water. C. Stain the slide with Cryo-Acid Alcohol rinse on the slide for a 1 seconds 1. Briefly rinse the slide with deionized water. D. Stain the slide with Cryo-Bluing Solution rinse on the slide for a 2 seconds 1. Briefly rinse the slide with deionized water E. Stain the slide with Cryo-Eosin rinse on the slide for a 10 seconds 1. Rinse off the excess stain with Ethanol. 2. Rinse off the excess stain with Clear-Rite. 3. Cover slip with Parmount and a glass cover slip." 3. Review of laboratory specimen logs had the following 173 patient frozen sections stained with H&E: 2021 - 62 patients: A random sampling of 10 are as follows: Date: Specimen # 01/4/2021: 21KS-1 2/19/2021: 21KS-113 3/18/2021: 21KS-182 05/6/2021: 21KS-295 5/11/2021: 21KS-306 7/7/2021: 21KS-452 8/6/2021: 21KS-524 9/30/2021: 21KS-629 11/11/2021: 21KS-708 12/23/2021: 21KS - 820 2022 - 111 patients: A random sampling of 10 are as follows: 1/13/2022: 22KS-18 1/24/2022: 22KS-35 2/17/2022: 22KS-90 3/14/2022: 22KS-152 4/14/2022: 22KS-213 5/5/2022: 22KS-263 6/6/2022: 22KS-347 9/22/2022: 22KS-628 10/4/2022: 22KS-669 11/2/2022: 22KS-732 4. In an interview on 4/6/2023

	at 09:58, in the pathology room, the laboratory director confirmed that the H&E staining protocol in the policy was not the one the laboratory followed when staining frozen tissue samples. This confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory documents, laboratory policy, patient reports, and confirmed in an interview, the laboratory failed to define, in policy, the intended reactivity for Hematoxylin and Eosin (H&E) staining to ensure predictable staining characteristics of quality control slides for 173 of 173 patients tested in 2021 and 2022. The findings included: 1. Review of the laboratory form titled "Quality Assurance Monitor for Frozen Section" included a column for "Quality of Stain" with subsequent "S+" handwritten with each patient documented. S+ as defined at the top of the page stated the following: S+ = Satisfactory 2. Review of the laboratory policy titled "Pathology Manual, Frozen Sections" did not include the intended reactivity of H&E staining to ensure predictable staining characteristics. 3. Review of laboratory specimen logs had the following 173 patient frozen sections stained with H&E: 2021 - 62 patients: A random sampling of 10 are as follows: Date: Specimen # 01/4/2021: 21KS-1 2/19/2021: 21KS-113 3/18/2021: 21KS-182 05/6/2021: 21KS-295 5/11/2021: 21KS-306 7/7/2021: 21KS-452 8/6/2021: 21KS-524 9/30/2021: 21KS-629 11/11 /2021: 21KS-708 12/23/2021: 21KS - 820 2022 - 111 patients: A random sampling of 10 are as follows: 1/13/2022: 22KS-18 1/24/2022: 22KS-35 2/17/2022: 22KS-90 3/14 /2022: 22KS-152 4/14/2022: 22KS-213 5/5/2022: 22KS-263 6/6/2022: 22KS-347 9/22 /2022: 22KS-628 10/4/2022: 22KS-669 11/2/2022: 22KS-732 4. In an interview on 4/6 /2023 at 09:55, in the pathology room, the laboratory director confirmed that the policy did not include the intended reactivity of H&E staining to ensure predictable staining characteristics. This confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
I. Based on review of the manufacturer's instructions for the Architect Lactic Acid assay, review of the manufacturer's instructions for the Architect Ammonia Ultra assay, review of patient test volumes, and staff interview, it was revealed the laboratory failed to have a mechanism in place to ensure samples did not contain platelets. The findings included: 1. A review of the manufacturer's instructions for the Architect Lactic Acid assay (G11015/R07, B9P180) under the section titled "Specimen Collection" revealed: "Ensure centrifugation is adequate to remove platelets." 2. A review of the manufacturer's instructions for the Architect Ammonia Ultra assay (307237/R04, B6K8Q0) under the section titled "Specimen Collection and Handling" revealed: "Ensure centrifugation is adequate to remove platelets." 3. The laboratory was asked to provide documentation of ensure samples were centrifuged in a manner which removed platelets from the serum prior to testing. No documentation was provided. 4. A review the laboratory's test volumes from 2021 and 2022 revealed the laboratory performed the following number of tests: a) Lactic Acid 2021 - 2060 tests see patient alias list #4 2022 - 1469 tests see patient alias list #5 b) Ammonia Ultra 2021 - 421 tests see patient alias list #6 2022 - 452 tests see patient alias list #7 5. An interview with general supervisor number 2 (as listed on Form CMS 209) on 04 /04/2023 at 1135 hours in the laboratory - after her review of the records- confirmed the findings. II. A review of the manufacturer's instructions for the Architect Amphetamine/Methamphetamine assay, review of the manufacturer's instructions for the Architect Barbiturates assay, review of the manufacturer's instructions for the Architect Benzodiazepines assay, review of the manufacturer's instructions for the Architect Cannabinoids assay, review of the manufacturer's instructions for the Architect Cocaine assay, review of the manufacturer's instructions for the Architect Opiates assay, review of the manufacturer's instructions for the Architect Phencyclidine assay, review of patient test volumes, and staff interview, it was revealed the laboratory failed to ensure urine samples were within a pH value of 3 - 11 prior to testing. The findings include: 1. A review of the manufacturer's instructions for the Architect Amphetamine/Methamphetamine assay (307301R12, B3L370) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 2. A review of the manufacturer's instructions for the Architect Barbiturates assay (307036R08, B3L380) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 3. A review of the manufacturer's instructions for the Architect Benzodiazepines assay (307267R15, B3L390) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 4. A review of the manufacturer's instructions for the Architect Cannabinoids assay (307075R10, B3L410) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 5. A review of the manufacturer's instructions for the Architect Cocaine assay (307302R11, B3L400) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 6. A review of the manufacturer's instructions for the Architect Opiates assay (307047R10, B3L340) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 7. A review of the manufacturer's instructions for the Architect Phencyclidine

assay (307019R08, B6L960) under the section titled "Specimen Collection and Handling" revealed: "Samples within a pH range of 3 - 11 are suitable for testing with this assay." 8. The laboratory was asked to provide documentation of mechanism in place to ensure urine samples tested were within the manufacturer's acceptable pH range of 3 - 11. No documentation was provided. 9. The laboratory reported performing testing on 1857 samples in 2022. 10. An interview with general supervisor number 2 (as listed on Form CMS 209) on 04/04/2023 at 1140 hours in the laboratory revealed the facility was unaware the pH of urine samples were required to be within 3 - 11 for testing. This confirmed the findings. 44278 III. Based on direct observation, manufacturer's instructions, laboratory reference interval studies, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for establishing the reference interval (patient normal range) for PT reagent (RecombiPlastin) upon installation for 2 of 2 ACL Top Family Series coagulation analyzers in 2019. Findings Included: 1. During a tour of the laboratory on 04/05 /2023 at 1535 hours, the inspector observed 2 Instrumentation Laboratory ACL Top 350 Coagulation Analyzers processing patient PT specimens. (SN:19081560 and SN: 19081561) 2. Review of manufacturer's instructions for the Hemosil Recombiplastin PT reagent revealed the following: "Expected Values Ranges were calculated as recommended by CLSI document C28-A. These results were obtained using a specific lot of reagent. Due to many variables which may affect clotting times, each laboratory should verify its own normal ranges." NOTE: This form references CLSI C28-A3 Clinical and Laboratory Standards Institute. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline, Document C28-A3. 3. Review of CLSI C28-A3 Clinical and Laboratory Standards Institute. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline, Document C28-A3, revealed the following: "However, as a standard for general practice, the working group supports the recommended minimum of 120 reference subjects. This number assumes that no observations are deleted from the reference set. If aberrant or outlying observations are deleted, then additional subjects should be selected until at least 120 acceptable reference values are obtained for each determination of a reference interval." 4. Review of laboratory's, "Verification of Reference Interval: Report Interpretation Guide" (Prepared by: Hemostasis-Instrumentation Laboratory on 11/20/2019) provided by the manufacturer, revealed the following: "Verification of Reference Interval (VRI) verifies a proposed or previously established reference interval, satisfying a CLIA '88 requirement. In this context, Reference Interval (RI) refers to the so-called "normal range", namely the range of the central 95% of results obtained from a group of ostensibly healthy individuals. Experiment Design: A reference interval is typically established from a study which calculates the central 95% of results measured on specimens from healthy persons (minimum 120 persons). In contrast, the verification study hypothesizes that the proposed normal range is correct for the lab's population. Key Statistics: ..Central 95% Interval: If sufficient results are available these values show nonparametric reference interval that would be established from the data. CLSI guidelines recommend using at least 120 specimens." Further review of the VRI or patient normal range study, revealed the laboratory failed to document analysis of 120 healthy patient specimens in the normal range study. (Unknown number of males and females and unknown if on any medications). 5. During an interview with the hematology regional lead technologist on 04/06/2023 at 0940 hours in the conference room, the lead technologist was asked to provide documentation of establishing the reference interval (patient normal range) with 120 healthy patient specimens for PT reagent (RecombiPlastin) upon installation of 2 of 2 ACL Top Family Series coagulation analyzers in 2019. No documentation was provided. This confirmed the above findings. Word Key PT- Prothrombin Time 45469 IV. Based on surveyor

	observation, stain instructions for use, biomedical records, patient final reports, and confirmed in interview, the laboratory failed to follow the manufactures instructions for the processing of urine for urine sediment examination for 17 of 17 random patients reviewed in November 2022. The findings included: 1. In a tour of the laboratory on 4/5/2023 at 10:50 hours surveyor noted a small purple vial near the microscope used in the examination of urine sediment with the following information: KOVA STAIN Concentrated Stain for Urinary Sediment Lot: K305440 Exp: 2023-10-31 Open'd: 1/6/23 Surveyor queried on 4/6/2023 at 11:55 hours, if the stain was utilized for all urine sediment analysis. Testing person (TP) 4 confirmed that one drop of the kova stain was placed on the sediment of the urine after it was spun for five minutes in the horizon mini ES centrifuge (equipment ID K00551) and the supernatant was decanted. 2. Review of the Kova stain instructions for use section "Standardized Urinalysis Procedure", subsection "Centrifugation and microscopic examination", had the following instruction: "Centrifuge the KOVA Tubes (each containing 12ml of urine specimen or KOVA-Trol) at a relative centrifugal force (rcf) of 400 for five minutes; approximately 1500 revolutions per minute (RPM) ..." 3. Review of the biomedical tachometer records for the "horizon mini ES" (equipment ID K00551) fixed speed centrifuge had an actual tachometry of 3,372 RPM recorded on 11/1/2022. 4. Review of final patient reports on 11/26/2022 and 11/27/2022 included the following 17 patients that had a urine sediment exam performed: 11/26 /2022: 12 patients 1126:U00215R 1126:U00133R 1126:U00116S 1126:U00164S 1126:U00167S 1126:U00197S 1126:U00200S 1126:U00217R 1126:U00215R 1126: U00217R 1126:U00215R 1126:U00112R 11/27/2022: 5 patients 1127:U00049R 1127: U00017S 1127:U00038S 1127:U00063S 1127:U00066S 5. In an interview on 4/5 /2023 at 15:10, in the office, general supervisor (GS) 1 confirmed that the centrifuge used in the centrifugation of urine for urine sediment examination exceeded that required by the manufacturer. This confirmed the findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's Architect Plus ci4000 analyzers' establishment studies performed in 2018, review of the laboratory's test volumes, and staff interview, it was revealed the laboratory failed to have documentation of performing required studies for 2 of 2 modified FDA-approved assays. The finding included: 1. A review of the laboratory's test menu revealed the laboratory performed testing utilizing the following modified FDA-approved assays on the Architect Plus ci4000 analyzers: SEKURE Chemistry Acetaminophen L3K assay STANBIO beta-hydroxybutyrate LiquiColor 2. A review of the laboratory's Architect Plus ci4000 analyzers' studies performed in 2018

	revealed the facility failed to have documentation of performing the following studies: a) stability and storage b) sensitivity c) specificity (including interfering substances). 3. The laboratory was asked to provide documentation of performing the required studies. No documentation was provided. 4. A review of the laboratory's test volumes from 2021 and 2022 revealed the laboratory performed the following number of tests utilizing the two assays: a) Acetaminophen L3K 2021 - 554 tests see patient alias list #1 2022 - 512 tests see patient alias list #2 b) beta-Hydroxybutyrate 2021 - no volume provide 2022 - 167 tests see patient alias list #3 5. An interview with general supervisor number 1 on 04/04/2023 at 1530 hours in her office - after her review of the records- confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's Architect Plus ci4000 maintenance records from May 2022 to June 2022, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing daily maintenance on 3 of 61 days. The finding included: 1. A review of the laboratory's Architect Plus ci4000 maintenance records from May 2022 to June 2022 revealed the laboratory failed to have documentation of daily maintenance being performed on the following days: a) May 21, 2022 - check 1 mL syringes - check DI water purity - daily maintenance b) June 11, 2022 - check 1 mL syringes - check DI water purity - daily maintenance c) June 12, 2022 - check 1 mL syringes - check DI water purity - daily maintenance 2. The laboratory was asked to provide documentation of daily maintenance being performed on the days identified. No documentation was provided. 3. A review of patient tests records from the listed days identified the following patients tested on days without daily maintenance being performed: a) May 21, 2022 42 samples tested see patient alias list #8 b) June 11, 2022 44 samples tested see patient alias list #9 c) June 12. 2022 39 samples tested see patient alias list #10 4. An interview with general supervisor number 2 (as listed on Form CMS 209) on 04/05 /2023 at 1130 hours in the laboratory - after her review of the records- confirmed the findings. Key mL - milliliter DI - de-ionized
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and confirmed in an interview, the laboratory failed to have a mechanism in place to monitor QC for accuracy and precision over time for the Avoximeter (AVOX) 4000 used in co-oximetry testing for 12 of 12 months reviewed in 2022. The findings included: 1. Review of the laboratory quality control logs titled "Kleberg AVOX 4000 Weekly Control Log" had the following three levels of QC in use from January to December 2022 for weekly QC testing: Level 1: Lot# 14867 - Exp 2023-01 -In use from 1/3/2022 - 12/6/2022 Lot# 24869 - Exp 2023-07 -In use from 12/12/2022 - 12/27/2022 Level 2: Lot# 14952 - Exp 2022-09 - In use from 1/3/2022 - 9/5/2022 Lot# 24965 - Exp 2022-08 - In use from 9/12/2022 - 12/27/2022 Level 3: Lot# 5057 - Exp 2022-05 - In use from 1/3 /2022 - 2/15/2022 Lot# 15058 - Exp 2022-09 - In use from 2/25/2022 - 9/5/2022 Lot# 15060 - Exp 2023-05 - In use from 9/12/2022 - 12/27/2022 2. In an interview on 4/4 /2023 at 12:35, in the respiratory therapy department, TP11 stated that the laboratory did not have a mechanism in place to monitor QC for accuracy and precision overtime for the Avox 4000 blood gas analyzer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Architect Plus ci4100 quality control records, review of patient test records, and confirmed in staff interview, the laboratory failed to perform two levels of quality control each day of patient testing for 2 out of 59 days for HIV testing. Findings included: 1. Review of the laboratory's Architect Plus ci4100 quality control records from January 2021 through March 2021 revealed the laboratory tested quality control each day of patient testing for HIV testing. 2. Further review of the laboratory's Architect ci4100 quality control records from January 2021 through March 2021 revealed the following dates quality control was not performed prior to patient testing: February 15, 2021 March 07, 2021 3. A review of patient testing records from January 2021 through March 2021 identified the following 2 patients were tested when quality control was not performed (see patient alias list #12): Date Patients tested 2/15/2021 1 3/07/2021 1 4. In an interview on 04/06/2023 at 1250 hours in the laboratory, after review of the above records, general supervisor number 2 (as listed on Form CMS 209) confirmed the findings. Word key HIV = Human immunodeficiency virus
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's MEDTOXscan quality control records from August 2022 to December 2022, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for 57 of 64 test days. The findings include: 1. A review of the laboratory's MEDTOXscan quality control records from August 2022 to December 2022 revealed the laboratory tested quality control weekly for the following moderately complex assays: Tetrahydrocanabinol Phencyclidine Cocaine Methamphetamine Opiates Amphetamine Benzodiazepine Barbiturates Tricyclic antidepressants Methadone Oxycodone Propoxyphene Buprenorphrine 2. The laboratory was asked to provide documentation of developing an Individualized Quality Control Plan (IQCP) to modify the frequency of quality control testing. No documentation was provided. 3. Further review of the laboratory's quality control records from August 2022 to December 2022 identified the laboratory performed quality control testing on the following days: August 7, 2022 August 14, 2022 August 21, 2022 August 28, 2022 September 3, 2022 September 10, 2022 September 18, 2022 September 24, 2022 October 1, 2022 October 9, 2022 October 22, 2022 October 30, 2022 November 5, 2022 November 12, 2022 November 19, 2022 December 3, 2022 December 24, 2022 December 31, 2022 4. A review of patient test records from August 2022 to December 2022 identified the following 103 patients tested on days without documentation of quality control testing being performed (see patient alias list #11): Date Patients tested 8/1/2022 3 8/3/2022 2 8/6/2022 1 8/10/2022 1 8/11/2022 2 8/15/2022 1 8/16/2022 2 8/17/2022 2 8/20/2022 1 8/22/2022 1 8/24/2022 1 8/26/2022 1 9/1/2022 2 9/6/2022 1 9/8/2022 3 9/9/2022 1 9/11/2022 1 9/12/2022 3 9/15/2022 1 9/19/2022 2 9/20/2022 1 9/23/2022 1 9/26/2022 2 9/29/2022 1 10/8/2022 1 10/10/2022 1 10/12/2022 1 10/13/2022 1 10/15/2022 1 10/17/2022 2 10/18/2022 1 10/21/2022 3 10/23/2022 3 10/24/2022 7 10/28/2022 2 10/31/2022 1 11/1/2022 1 11/2/2022 1 11/4/2022 2 11/10/2022 4 11/12/2022 2 11/20/2022 5 11/21/2022 1 11/28/2022 2 12/02/2022 3 12/07/2022 1 12/08/2022 1 12/10/2022 2 12/11/2022 6 12/12/2022 3 12/16/2022 3 12/17/2022 1 12/21/2022 1 12/22/2022 1 12/28/2022 2 5. An interview with general supervisor number 2 (as listed on Form CMS 209) on 04/04/2023 at 1530 hours in the laboratory revealed the facility was unaware quality control tested was required to be performed each day of patient testing unless the laboratory established an Individualized Quality Control Plan. She stated the laboratory followed the manufacturer's instructions to perform quality control testing each week. This confirmed the findings. II. Based on review of the laboratory's Architect Plus ci4100 quality control records, review of patient test records, and confirmed in staff interview, the laboratory failed to perform two levels of quality control each day of patient testing for 13 of 90 days for Cocaine testing and 2 of 67 days for Hepatitis B Surface Antigen (HBsAg) testing. Findings included: 1. Review of the laboratory's Architect Plus ci4100 quality control records from January 2021 through March 2021 revealed the laboratory tested quality control each day of patient testing for the following assays: HBsAg Cocaine 2. Further review of the laboratory's Architect Plus ci4100 quality control records from January 2021 through March 2021 revealed the following dates quality control was not performed prior to patient testing: a. Cocaine testing; January 16, 2021 January 17, 2021 January 18, 2021 January 19, 2021 January 20, 2021 January 21, 2021 January 22, 2021 January 23, 2021 January 24, 2021 January 25, 2021 January 30, 2021 February 02, 2021 February 09, 2021 b. HBsAg testing; February 15, 2021 February 21, 2021 3. A review of patient test records from January 2021 through March 2023 identified the following 104 patients were tested when quality control was not performed (see patient alias list #13): a.

	Cocaine: Date Patients tested 1/16/2021 10 1/17/2021 6 1/18/2021 8 1/19/2021 9 1/20 /2021 5 1/21/2021 6 1/22/2021 9 1/23/2021 5 1/24/2021 8 1/25/2021 5 1/30/2021 6 2/2 /2021 11 2/9/2021 14 b. HBsAg: Date Patients tested 2/15/2021 1 2/21/2021 1 4. In an interview on 04/06/2023 at 1250 hours in the laboratory, after review of the above records, general supervisor number 2 (as listed on Form CMS 209) confirmed the findings.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of policies and procedures, the 2022 quality control records, patient test records and interview of facility personnel, the laboratory failed to test quality control materials in duplicate when performing body fluid cell counts using the Hemocytometer on 13 of 13 days between 01/01/2022 and 06/26/2022. In addition, the laboratory failed to test quality control materials on 2 of 13 dates when patient specimens were tested between 01/01/2022 and 06/26/2022. The findings included: 1. Review of the procedure H17 BODY FLUID CELL COUNT, DIFFERENTIAL, AND GROSS EXAMINATION (EFFECTIVE DATE 09/97) found on page 2 under PROCEDURE:" All cell counts must be performed in duplicate and the counts obtained on each chamber should agree within 20%. NOTE: Record results of both sides of the chamber on the body fluid worksheet." 2. Review of 2022 Hemocytometer quality control records found the laboratory recorded one value in each of the fields for RBC and WBC on the Hemocytometer QC Sheet for the following dates: 01/05/2022 01/07/2022 01/10/2022 01/14/2022 02/08/2022 03/18 /2022 03/27/2022 03/31/2022 04/09/2022 04/17/2022 04/21/2022 05/18/2022 06/26 /2022 There was no documentation of quality control materials tested on two days when patient specimens were tested: 01/06/2022 05/28/2022 3. Review of patient test records found the laboratory tested 13 patient body fluid specimens for cell counts using the Hemocytometer as follows: 01/05/2022 - AQ0001373118 01/06/2022 - AQ0001373358 01/10/2022 - AQ0001373597 01/14/2022 - AQ0001373713 03/18 /2022 - AQ0001379380 03/27/2022 - AQ0001380155 03/31/2022 - AQ0001380507 04/09/2022 - AQ0001381406 04/17/2022 - AQ0001382103 04/21/2022 - AQ0001382514 05/18/2022 - AQ0001384830 05/28/2022 - AQ0001386041 06/26 /2022 - AQ0001388634 4. During interview of general supervisor 1 on the Laboratory Personnel Report conducted April 5, 2023 at 11:25 she confirmed the laboratory does not document two counts for quality control materials, only patients.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, quarterly alarm checks (2021-2022) and staff interview, it was revealed that the laboratory failed to follow their own written policy for quarterly alarm checks on the blood bank refrigerator in 2021 and 2022. Findings Included: 1. During a tour of the laboratory on 04/04/2023 at 1420 hours, the inspector observed 1 refrigerator containing reagents, blood and blood products. (SN:1123909401200100) 2. Review of laboratory policy, "Activation Alarm Check for Blood Bank Refrigerator" (Version 3; Effective 11/05/2018) revealed the following: "Principle: Refrigerators must have alarm systems with audible signals. The alarms are to be set to activate at a temperature that will allow proper action to be taken before blood and blood components reach undesirable temperatures. The alarm systems are tested quarterly with a thermometer." 3. Review of laboratory quarterly alarm checks for 2021 and 2022, revealed the laboratory failed document alarm testing quarterly. 4. During an interview with the blood bank regional lead technologist on 04/05/2023 at 1330 hours in the conference room, the supervisor confirmed the laboratory failed to follow their own written policy for quarterly alarm checks on the blood bank refrigerator in 2021 and 2022.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory and facility blood product transfusion policies, facility blood transfusion forms, a random review of patient transfusion records (01/01/2023-01/15/2023 and 08/01/2023-08/15/2023), and confirmed in staff interview, it was revealed the laboratory failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 6 of 25 patients that received blood products. Findings Included: 1. Review of facility policy, "Blood Transfusion Administration Procedure" (Revised 05/2022) revealed the following: "13. To initiate, maintain and discontinue the transfusion of unit of blood products:.. b. Document pre-transfusion vital signs. ..g. The RN should remain with or be in a position to closely observe the patient for at least the first 15 minutes of infusion. Signs and symptoms of a fatal transfusion reaction usually occur within this time period. h. The RN or LVN will periodically observe and assess patient for symptoms of transfusion reactions. i. Additional vital signs should be documented as follows: i. Just prior to initiating the infusion. ii. Within fifteen (15) minutes after transfusion has started. iii. Every 30 to 60 minutes or more frequently as indicated by patient's condition. iv. At the end of the transfusion. v. One-hour post-transfusion. ..o. Signs and symptoms as described in the next section may occur several hours to several

days post transfusion and should be reported to the Transfusion Service for investigation. 14. Transfusion Reaction a. Complications to a transfusion may include the following: i. Urticaria ii. Chills iii. Temperature 2 degrees over baseline iv. Headache v. Nausea vi. Pain vii. Shortness of breath 2. Review of the laboratory policy, "Transfusion Reaction Investigation" (Version 5; Effective 11/05/18) revealed the following: "Procedure: ..8. Review clinical signs and symptoms pre- and post-transfusion. See guidelines to classification of transfusion reaction." 3. During an interview with the regional blood bank supervisor on 04/04/2023 at 1426 hours in the laboratory, the supervisor was asked to provide the guidelines for transfusion reaction classification. The following facility guidelines were provided: "Transfusion Reaction Report Complete information below when a transfusion complication occurs. Type of complication: Urticaria; Chills; Fever; Headache; Shortness of breath; Cyanosis; Nausea; Back Pain; Pain at infusion site; Increased pulse rate; Decreased blood pressure; Significant increase in systolic BP (greater that 40 mm/Hg)" The facility, laboratory policies and facility guidelines failed to define criteria for respiration rate to indicate a transfusion reaction. The facility, laboratory policies and facility guidelines failed to define criteria for pulse rate changes. The laboratory policy and facility guidelines failed to define criteria for an increase in temperature to indicate a transfusion reaction. The facility policy failed to define criteria for systolic blood pressure changes. 4. A random review of blood product administration patient records (01/01/2023-01/15/2023 and 08/01/2023-08/15/2023), revealed the following 6 of 25 patients in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. Patient 0103:BB00041R Unit Number: W230821720320; Red Blood Cells Transfusion Begin Date/Time: 01/05/2022/0835 Transfusion End Date/Time: 01/05/2022/1002 Time: 1002 hours Transfusion comment: Time: 1002 hours: PATIENT TRANSPORTED TO EMERGENCY ROOM. PATIENT WAS EXPERIENCING SOB. The patient experienced shortness of breath following the start of a transfusion and was transported to the emergency room. Per facility policy, indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. b. Patient 0106:BB00045S Unit Number: W230821164034; Red Blood Cells Transfusion Begin Date/Time: 01/06/2022/1620 Transfusion End Date/Time: 01/06/2022/1832 Pre-Transfusion Vitals documented at 1617: Temperature: 98.0; Blood Pressure: 125/58; Pulse/HR 85; Respiratory rate: 18 Vitals documentation at 1832: Temperature: 98.0; Blood Pressure: 173/74; Pulse/HR 83; Respiratory rate: 18 The patient had a blood pressure increase of 48 mmHg from vitals documented at 1617 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. c. Patient 0109:BB00045S Unit Number: W230821369206; Red Blood Cells Transfusion Begin Date/Time: 01/11/2022/0054 Transfusion End Date/Time: 01/11/2022/0311 Pre-Transfusion Vitals documented at 0139: Temperature: 98.7; Blood Pressure: 107/52; Pulse/HR 88; Respiratory rate: 12 Vitals documentation at 0310: Temperature: 98.7; Blood Pressure: 159/72; Pulse/HR 100; Respiratory rate: 20 The patient had a blood pressure increase of 52 mmHg from vitals documented at 0310 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. d. Patient 0808:BB00045S Unit Number: W230822453272; Red Blood Cells Transfusion Begin Date/Time: 08/08/2022/1141 Transfusion End Date/Time: 08/08/2022/1515 Pre-Transfusion Vitals documented at 1145: Temperature: 97.8; Blood Pressure: 94/64; Pulse/HR 112; Respiratory rate: 24 Vitals documentation at 1500: Temperature: 98.1; Blood Pressure: 136/76; Pulse/HR 94; Respiratory rate: 21 The patient had a blood pressure increase of 42 mmHg from vitals documented at 1500 hours. Per facility guidelines,

	an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. e. Patient 0810:BB00087R Unit Number: W230822682435; Red Blood Cells Transfusion Begin Date/Time: 08/10/2022/2250 Transfusion End Date/Time: 08/11/2022/0042 Pre-Transfusion Vitals documented at 2342: Temperature: 99.1; Blood Pressure: 115/58; Pulse/HR 87; Respiratory rate: 20 Vitals documentation at 0042: Temperature: 99.8; Blood Pressure: 158/67; Pulse/HR 87; Respiratory rate: 18 The patient had a blood pressure increase of 43 mmHg from vitals documented at 1500 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. f. Patient 0815:BB00029R Unit Number: W230822682658; Red Blood Cells Transfusion Begin Date/Time: 08/15/2022/1128 Transfusion End Date/Time: 08/15 /2022/1351 Pre-Transfusion Vitals documented at 1213: Temperature: 98.2; Blood Pressure: 105/57; Pulse/HR 78; Respiratory rate: 16 Vitals documentation at 1451 (1 hour post vitals): Temperature: 98.4; Blood Pressure: 152/52; Pulse/HR 86; Respiratory rate: 16 The patient had a blood pressure increase of 47 mmHg from vitals documented at 1451 hours. Per facility guidelines, an increase in blood pressure by 40 mmHg indicated a possible transfusion reaction. No documentation of a transfusion reaction investigation was provided. 5. During an interview with the blood bank regional lead technologist on 04/05/2023 at 1324 hours in the conference room, the lead technologist confirmed the laboratory failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 6 of 25 patients that received blood products.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, review of the laboratory's test menu, review of the laboratory's records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of two instrument comparisons being performed in 2021 and 2022 between the Architect Plus ci4000 analyzer and the MEDTOXscan analyzer. The findings included: 1. A review of the laboratory policy titled "Chemistry Instrument to Instrument" (effective date: 9/24/2018) under the section titled "Principle" revealed: "At least every 6 months a comparison between analyzers with the same analytes on board will be performed to verify the recovery of patient analyte values." 2. A review of the laboratory's test menu revealed the following analytes tested on both the Architect Plus ci4000 analyzer and the MEDTOXscan analyzer: Tetrahydrocanabinol Phencyclidine Cocaine Methamphetamine Opiates Amphetamine Benzodiazepine Barbiturates 3. A review of the laboratory's records from 2021 and 2022 revealed the laboratory failed to have documentation of performing 2 comparisons annually for the identified analytes tested on both instruments. 4. The laboratory was asked to provide documentation of performing the comparisons in 2021 and 2022. No documentation was provided. 5. An interview with general supervisor number 1 (as listed on Form CMS 209) on 04/05 /2023 at 0920 hours in her office confirmed the findings. II. Based on review of the

	laboratory's policies, review of the laboratory's test menu, review of the laboratory's records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of two instrument comparisons being performed in 2021 for analytes tested on each of the laboratory's Architect Plus ci4000 analyzers. The findings included: 1. A review of the laboratory policy titled "Chemistry Instrument to Instrument" (effective date: 9/24/2018) under the section titled "Principle" revealed: "At least every 6 months a comparison between analyzers with the same analytes on board will be performed to verify the recovery of patient analyte values." 2. A review of the laboratory's test menu identified the following analytes tested on both of the laboratory's Architect Plus ci4000 analyzers: glucose sodium potassium chloride blood urea nitrogen creatine CO2 calcium phosphorous magnesium total protein albumin aspartate transaminase alanine transaminase aklanine phosphatase amylase creatine kinase total billirubin creatine kinase - muscle/brain troponin beta human chorionic gonadotropin vancomycin 2. A review of the laboratory's comparison records from 2021 revealed one comparison study was performed in June 2021. The laboratory was asked to provide documentation of a second comparison being performed in 2021. No documentation was provided. 3. An interview with general supervisor number 1 (as listed on Form CMS 209) on 04/05/2023 at 0920 hours in her office revealed a second comparison study for 2021 could not be found. This confirmed the findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory final reports and patient slides, review of laboratory policy, and confirmed in an interview, the laboratory failed to accurately document the date of specimen receipt into the laboratory for 4 of 20 patients submitted for frozen sections reviewed from January and July from 2012 to 2022. The findings included: 1. In a review of the laboratory's frozen section records the surveyor requested the first frozen cases for the months of January and July from 2012 to 2022. Surveyor noted the following discrepant receipt (processing) dates between the final patient reports and the slides obtained for frozen sectioning on the following four patients: Specimen 19-KS-22: Date on slide: 1/11/2019 Date on final report: 1/11 /2019 Specimen 20-KS-9: Date on slide: 1/8/2020 Date on final report: 1/9/2020 Specimen 20-KS-381 Date on slide: 7/1/2020 Date on final report: 7/2/2020 Specimen 22-KS-18 Date on slide: 1/13/2022 Date on final report: 1/14/2022 2. Review of the laboratory policy titled "Pathology manual, Frozen Sections", subsection "Procedure" had the following instruction: "II. Slide Preparation: A. Slides must be ready for microscopic examinations within fifteen (15) minutes after receipt of the specimen." 3. In an interview on 4/6/2023 at 09030, in the laboratory, the assistant to the laboratory director stated that specimens occasionally are received after hours for frozen section and that the date on the slide is when the specimen receipt and testing took place, and that the received date on the final report reflects when the specimen was accessioned into the laboratory information center. This confirmed the findings.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's Unity records, and confirmed in staff interview, the laboratory failed to establish and follow policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified for Microalbumin/Urine Albumin quality control for 3 of 5 months and for Total Protein quality control for 9 of 12 months. Findings included: 1. Review of "Chemistry Quality Control Material" policy (Effective date October 26, 2020; version 1) stated, "C. Quality Control Review ... In addition, all BioRad control data are submitted to the manufacturer for peer review ... Troubleshooting and patient result review follows, as appropriate." 2. Review of laboratory records titled Unity Monthly Evaluation Urine Chemistry for February 2021 through June 2021 identified the following months when Microalbumin/Urine Albumin quality control results were outside of the acceptable values: a) March 2021. Lab 291848 Level 2 Peer SDI 2.25 Warning: Acceptable values are above -2 and below 2 Corrective Action "Reviewed, New lot started 4/1/2021." b) April 2021. Lab 291848 Level 1 Peer SDI 2.37 Warning: Acceptable values are above -2 and below 2 Level 2 Peer SDI 2.24 Warning: Acceptable values are above -2 and below 2 Corrective Action "Reviewed and Accepted" c) May 2021. Lab 291848 Level 1 Peer SDI 2.32 Warning: Acceptable values are above -2 and below 2 Level 2 Peer SDI 2.93 Warning: Acceptable values are above -2 and below 2 Corrective Action "Data reviewed. Deemed acceptable. Will continue to monitor." The laboratory failed to assess and correct problems identified with Microalbumin/Urine Albumin quality control. 3. Review of the laboratory records titled Unity Monthly Evaluation Multiqual 1, 2, 3 Unassayed for January 2021 through December 2021 identified the following months when Total Protein quality control results were outside of the acceptable values: a) January 2021. Lab 291848 Level 3 Peer CVR 2.5 Warning: Acceptable values are below 2 Level 3 Peer SDI -2.01 Warning: Acceptable values are above -2 and below 2 Corrective Action "Level 3 OK. Will continue to review." b) February 2021. Lab 291848 Level 2 Data Exclusion: Lab Mean = 5.22. Acceptable values are 5.262 to 5.721 Level 3 Data Exclusion: Lab Mean = 6.41. Acceptable values are 6.654 to 7.190 Corrective Action "X shifted to acceptable limits. Will continue to monitor." c) March 2021. Lab 291848 Level 1 Peer CVR 2.1 Warning: Acceptable values are below 2 Corrective Action "TBIL, CA, TP reviewed found to be acceptable. Will continue to monitor." d) April 2021. Lab 291848 Level 1 Peer CVR 2.4 Warning: Acceptable values are below 2 Level 2 Peer CVR 2.2 Warning: Acceptable values are below 2 Corrective Action "For Calcium and TP Results are acceptable. Will continue to monitor." e) June 2021. Lab 291848 Level 3 Peer CVR 2.6 Warning: Acceptable values are below 2 Corrective Action " ...Errant data excluded for Level 1 Total Protein Recalculated CV=3.11. Recalculated CVR = 1.8." f) July 2021. Lab 291848 Level 1 Peer CVR 2.1 Warning: Acceptable values are below 2 Corrective Action "Data reviewed. Deemed acceptable." g) August 2021. Lab 291848 Level 1 Peer CVR 2.7 Warning: Acceptable values are below 2 Level 3 Peer CVR 2.7 Warning: Acceptable values are below 2 Corrective Action "Data reviewed. Event points omitted, outliers deemed acceptable." h) September 2021. Lab 291848 Level 3 Peer CVR 2.4 Warning: Acceptable values

	are below 2 Corrective Action "For TP X + SD Adjusted to match peer group. Presently TP Level 3 matched peer group." i) November 2021. Lab 291848 Level 1 Peer CVR 2.2 Warning: Acceptable values are below 2 Level 3 Peer CVR 2.2 Warning: Acceptable values are below 2 Corrective Action "Warning reviewed. Presently SD for Dec 21 0.06 which is acceptable. Will continue to monitor." The laboratory failed to correct problems identified with Total Protein quality control. 4. During an interview on April 06, 2023 at 1010 hours in the laboratory, after review of the above records, the General Supervisor 2 (as listed on Form CMS 209) confirmed the findings. Word Key TP = Total Protein
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Review of pathology reports and interview of facility personnel found that the laboratory failed to ensure the name and address of the laboratory performing the final interpretation of tissue specimens obtained during surgical procedures appeared on twelve of twelve surgical pathology reports between February 2, 2022 and November 30, 2022. The findings included: 1. Review of twelve final pathology reports found no documentation of the name and address of the laboratory performing the final interpretation for the following reports: Accession 22-KS-102 reported 03/01/2022 Accession 22-KS-171 reported 03/24/2022 Accession 22-KS-300 reported 05/20/2022 Accession 22-KS-386 reported 06/21/2022 Accession 22-KS-519 reported 08/13/2022 Accession 22-KS-529 reported 08/15/2022 Accession 22-KS-526 reported 09/08/2022 Accession 22-KS-593 reported 09/12/2022 Accession 22-KS-666 reported 10/08/2022 Accession 22-KS-669 reported 10/06/2022 Accession 22-KS-729 reported 11/03/2022 Accession 22-KS-786 reported 12/01/2022 2. Interview of the laboratory director conducted April 6, 2023 at 0925 confirmed that the frozen section diagnosis was performed at this laboratory with the final diagnosis being done at another facility. He went on to confirm that the name and address of the laboratory performing the final diagnosis did not appear on the final report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management of the laboratory. The

	findings include: 1. The laboratory director failed to ensure policies and procedures for test systems were followed to provide quality laboratory services (refer to D6007). 2. The laboratory director failed to ensure a quality control program was developed and followed refer to D6020). 3. The laboratory director failed to ensure a quality assurance program indentified and corrected problems (refer to D6021).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interviews, it was revealed the laboratory director failed to ensure policies and procedures for test systems were followed to provide quality laboratory services. The findings include: The findings include: 1. The laboratory director failed to ensure a mechanism was in place to ensure samples received by the laboratory were kept at a temperature that maintained sample stability (refer to D5311 I) 2. The laboratory director failed to ensure the policy for fibrinogen specimen acceptability was followed (refer to D5311 II). 3. The laboratory director failed to ensure the laboratory followed its policy for performing sampling mode comparisons (refer to D5401 I). 4. The laboratory director failed to ensure the laboratory followed its policy for hematoxylin and eosin (H&E) staining for frozen section processing (refer to D5401 II). 5. The laboratory director failed to ensure the laboratory defined, in policy, the intended reactivity for Hematoxylin and Eosin (H&E) staining to ensure predictable staining characteristics of quality control slides for 173 of 173 patients tested in 2021 and 2022 (refer to D5403). 6. The laboratory director failed to ensure the laboratory followed manufacturer's instructions to ensure samples did not contain platelets (refer to D5411 I). 7. The laboratory director failed to ensure the laboratory followed manufacturer's instructions to ensure urine samples were within a pH value of 3 - 11 prior to testing (refer to D5411 II). 8. The laboratory director failed to ensure the laboratory followed manufacturer's instructions for establishing the reference interval (patient normal range) for PT reagent (RecombiPlastin) upon installation for 2 of 2 ACL Top Family Series coagulation analyzers in 2019 (refer to D5411 III). . The laboratory director failed to ensure the laboratory followed manufacturer's instructions for the processing of urine for urine sediment examination for 17 of 17 random patients reviewed in November 2022 (refer to D5411 IV).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was developed and followed. The findings were: 1. The laboratory director failed to ensure the laboratory had a mechanism in place to monitor QC for accuracy and precision over time for the Avoximeter (AVOX) 4000 used in co-oximetry testing for 12 of 12 months (refer to D5441). 2. The laboratory director failed to ensure the laboratory performed two levels of quality control each day of patient testing for 2 out of 59 days for HIV testing (refer to D5447). 3. The laboratory director failed to ensure the laboratory performed quality control testing each day of patient testing for 57 of 64 test days on the MEDTOXscan analyzer (refer to D5449). 4. The laboratory director failed to ensure the laboratory tested quality control materials as required for body fluid cell counts (refer to D5543).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure quality assessment program identified and corrected problems. The findings were: 1. The laboratory director failed to ensure the quality assessment plan identified that laboratory failed to establish and follow policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified (refer to D5791).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, submitted Centers for Medicare and Medicaid Services (CMS -209) form, personnel records, direct observation and staff interview, the technical supervisor failed to perform testing personnel competency assessments at least semiannually during the first year of patient testing for 2 of 10 testing persons who perform high complexity testing. Findings Included: 1. Review of the Centers for Medicare and Medicaid (CMS -209) form submitted at the time of survey, 04/04 /2023, revealed 10 testing persons (TP-1 through TP-10) and 1 technical supervisor

	(TS-1) who was also serving as the laboratory director for high complexity testing. 2. Review of laboratory policy, "Employee Competency Evaluation" (Version 4; Effective: 10/05/2018" revealed the following: "New employees competence is monitored for the first three months and evaluated thereafter. All employees performance is assessed annually in their job specific performance evaluation." 3. Review of personnel records revealed two new testing persons in 2022 (TS-8 and TS-9). Further review of records revealed the general supervisor 2 (GS-2) performed competency of both TP 8 and 9. a. TP-8 Hire Date: 06/02/2022 Initial Competency Date: 12/01/2022 Evaluator: GS-2 The technical supervisor (TS-1) failed to perform the initial competency of TP-6 in 2022. b. TP-9 Hire Date: 11/21/2022 Initial Competency Date: 12/30/2022 Evaluator: GS-2 The technical supervisor (TS-1) failed to perform the initial competency of TP-7 in 2022. 4. During an interview with GS-1 on 04/04/2023 at 1135 hours in the conference room, GS-1 confirmed the above findings.